

(b) *Specifications.* Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 60 FR 39847, Aug. 4, 1995; 64 FR 15684, Apr. 1, 1999]

#### § 522.770 Doramectin.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in fe-

male dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999]

#### § 522.775 Doxapram hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per lb. with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

## § 522.778

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 17838, Apr. 23, 1975]

### § 522.778 Doxycycline hyclate.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) *Indications for use.* For treatment and control of periodontal disease.

(iii) *Limitations.* Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 8349, Feb. 19, 1998, as amended at 65 FR 45878, July 26, 2000]

### § 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.<sup>1</sup>

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be in-

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

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jected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.<sup>1</sup>

(3) Not for use in horses intended for food.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

### § 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds